

COVER PAGE

Title of Study: Home Blood Pressure Monitoring Intervention for Self-Management of High Blood Pressure Among Alaska Native People

NCT number: NCT03872856

Date of Document: July 9, 2021

Part 1: Blood Pressure Screening

Key Information:

We are asking you to voluntarily join a research study on blood pressure. We want to know if your current blood pressure is high or not. If you decided to join, you will be asked to take your blood pressure at home twice a day for a week. We will give you a home blood pressure device. You will also meet with us in one year for a follow-up visit about how much you used the blood pressure device. We are also asking permission to look at certain information in your medical record about you and your blood pressure. Depending on your blood pressure, you may be eligible for the next part of this blood pressure study. We anticipate little to no risks to you as a volunteer in this study.

What is the goal of the research study?

The goal is to measure current blood pressure among people with a diagnosis of hypertension or high blood pressure. This study will also help identify people who may be eligible for the next part of this blood pressure study.

Why is this research study being done here at Southcentral Foundation?

High blood pressure can lead to heart disease and stroke, which are leading causes of death among Alaska Native and American Indian people. The study is being done by researchers from the Southcentral Foundation Research Department and Washington State University.

Who can join the research study?

We are inviting Alaska Native and American Indian people, age 18 years or older that meet the eligibility criteria to participate.

- 1) At least one visit to Southcentral Foundation or with a Community Health Aides last year;
- 2) Diagnosis of high blood pressure and systolic blood pressure equal to or higher than 140mmHg OR systolic blood pressure 130-139mmHg plus other health conditions

OR

No diagnosis for high blood pressure but have systolic blood pressure readings equal to or higher than 140mmHg OR systolic blood pressure 130-139mmHg plus other health conditions

3) Willingness and ability to consent

4) Willingness to complete necessary data collection procedures; and

5) Not currently pregnant

Will I have to pay anything to be in this research study?

No. Participation in this study will not cost you any money.

What will I be asked to do if I join this research study?

If you decide to join this study, you will be asked to take your blood pressure at home twice a day for a week, or until you have collected a minimum of 12 blood pressure readings. You will share your blood pressure log with us. You will also meet with us in one year for a follow-up visit about how much you used the blood pressure device.

To thank you for your time and participation, you get to keep the home blood pressure device and will receive a \$75 gift card for completing the 1-week blood pressure log and providing your readings.

Will you be looking at my medical records?

Yes, with your permission the Southcentral Foundation Data Services Department will use your medical record number, name, or date of birth to access your medical record. Only information related to the purpose of this study will be collected. For example, we will look at what medicines you are taking and other health issues related to heart disease. The Data Services Department will give this information to the Southcentral Foundation and Washington State University research team. The information the researchers are given will not include your name or any other information that could identify you. You can still be in the study if you do not give permission for the medical record review. If you would like to know all the information that we will look at, please ask the research staff member.

Can I choose not to join this research study?

Yes. You are free to join the study or not join the study. You are free to withdraw from the research project at any time. If you join the study, then decide not to give permission for the medical record review, you will not be forced to. If you choose not to join, you will not lose any benefits you are now getting at Southcentral Foundation. Your choice to join this research study will not affect whether you can join future research studies.

Are there any risks?

There is a potential risk of discomfort when the blood pressure cuff inflates and squeezes around your arm. You will be able to stop the device from inflating further if it causes discomfort.

There is a small chance that information about you could be found out by others who are not part of the research team. We will take many steps to prevent this from happening.

- There is a risk that other people may learn you have joined this study. However, the form you fill out and this consent form will be kept locked-up to prevent this from happening.
- There is a risk that those with access to the study data will learn who you are. To prevent this from happening we will use a special code number on all materials to protect your privacy.
- All researchers in this study have agreed to only study information related to this study. They can be fired or face criminal charges if they do not keep this agreement.
- Government or organizational staff at times may review studies to make sure they are being done safely and legally. If a review of this study happens, your records may be looked at. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

Will I receive any personal results from this study?

You will have all your blood pressure results from the home monitoring device.

How will I benefit or gain from being in this research study?

You may benefit from your participation in the research by monitoring your blood pressure at home and learning more about what your blood pressure usually is.

Who can I call if I have any questions?

If you have any questions about the study, please contact one of the researchers at (907) 729-8623 or Denise Dillard at (907) 729-8518. For questions about your rights as a study participant, contact the Alaska Area Institutional Review Board Administrator at akaalaskaarealRB@anthc.org.

This research study is:

- Looking at high blood pressure
- Funded by the National Institutes of Health
- Completely voluntary

This research study will:

- **NOT** look at unrelated information in your medical record
- **NOT** cost you any money

- **NOT** send your name to Washington State University

If you choose to participate:

- Take your blood pressure at home twice a day for a week or until you have a minimum of 12 blood pressure readings
- You will be asked to let SCF Research see limited information from your medical record
- Meet in a year to answer questionnaires

To help locate your medical record for this study, please provide your date of birth and medical record number (if known) below.

Date of Birth: _____

Medical Record Number (Chart Number) _____

Signature below means you agree to join this study, and your questions have been answered.

[For verbal consent, read the statement and have the participant repeat the bold part below.]

I have been told about this research and all my questions have been answered. I have been offered a copy of this consent. **I agree to be in the study.**

☐ verbal consent received

Signature of Participant or Legal Representative (if in person)

Date

Signature of Research Staff

Date

Blood Pressure Monitoring Intervention for Management of High Blood Pressure among Alaska Native People

What is this research study about?

Heart disease and stroke have become leading causes of death among Alaska Native and American Indian people. High blood pressure can lead to stroke. Improving self-management of high blood pressure is important to reduce stroke risk, especially for Alaska Native people that have limited access to healthcare.

Please carefully read this form and ask any questions you have.

What is the goal of the research study?

The goal of this study is to improve management of high blood pressure among Alaska Native and American Indian people with high blood pressure. We want to understand different blood pressure management strategies at Southcentral Foundation to improve health services for treating high blood pressure.

Why is this research study being done here at Southcentral Foundation?

Heart disease and stroke have become leading causes of death among Alaska Native and American Indian people. The study is being done by researchers from the Southcentral Foundation Research Department and Washington State University.

Who can join the research study?

We are inviting 324 Alaska Native and American Indian people age 18 years or older that meet the following eligibility criteria to participate.

- 1) At least one visit to Southcentral Foundation or Community Health Aides last year;
- 2) At least 18 years old;
- 3) Diagnosis of high blood pressure and systolic blood pressure equal to or higher than 140mmHg OR systolic blood pressure 130-139mmHg plus other health conditions

OR

No diagnosis for high blood pressure but have systolic blood pressure readings equal to or higher than 140mmHg OR systolic blood pressure 130-139mmHg plus other health condition(s)

- 4) Willingness and ability to consent;
- 5) Willingness to complete necessary data collection procedures; and
- 6) Not currently pregnant

If your blood pressure is not higher than or equal to 140mmHg or 130mmHg if there are other conditions on the first study visit, you are only eligible for 1 of the 5 study visits.

Will I have to pay anything to be in this research study?

No. Participation in this study will not cost you any money.

What will I be asked to do if I join this research study?

If you decide to join this study, there will be up to 5 study visits in total. You may do these over the phone, a virtual meeting, or in person when allowed. After this first visit, you may have visits at 3 months, 6 months, one year later, and the final visit in-person if eligible.

If you are eligible for follow up visits, you will be asked to provide contact information (name, address, phone number, email address) so that we are able to contact you.

During your visits, we will ask you to do the following things:

- Fill out a survey. It will include questions about you (e.g., age, diet, recent use of health services, tribe or Alaska Native group you belong to) and your thoughts about various ways to manage blood pressure. The questionnaire will be longer on the first and last visit.
- Allow measurement of blood pressure, height, weight, and arm.

- Give the Southcentral Foundation and Washington State University researchers permission to have certain health and blood pressure related information pulled from your medical record.

To thank you for your time and participation, you will receive a gift card at each study visit.

- \$50 gift card at the end of this 1st study visit (1.5 – 2 hours on average)

If you are eligible for the three follow-up study visits you will receive a gift card at each of these three visits.

- \$25 gift card at the end of the 2nd and 3rd study visits (30 minutes – 1 hour on average)
- \$50 gift card at the end of the final study visit. (1.5 – 2 hours on average)
- \$25 gift card at the end of the final in-person visit (20 - 30 minutes)
- You will also receive a home blood pressure monitor at the end of the study.

Will you be looking at my medical records?

Yes, with your permission the Southcentral Foundation Data Services Department will use your medical record number (MRN), name, date of birth, or address to access your medical record. Only information related to the purpose of this study will be collected. For example, we will look at what medicines you are taking and other health issues related to heart disease. The Data Services Department will give this information to the Southcentral Foundation and Washington State University research team. The information the researchers are given will not include your name or any other information that could identify you. You can still be in the study if you refuse to consent to the medical record review. If you would like to know all the information that we will look at, please ask the research staff member.

Can I choose not to join this research study?

Yes. You are free to join the study or not join the study. You are free to withdraw from the research project at any time. If you join the study, then decide not to give permission for the medical record review, you will not be forced to. If you choose not to join, you will not lose any benefits you are now getting at Southcentral Foundation. Your choice to join this research study will not affect whether you can join future research studies.

Are there any risks?

There is a potential risk of discomfort when the blood pressure cuff inflates and squeezes around your arm. You will be able to stop the device from inflating further if it causes discomfort.

There is a small chance that information about you could be found out by others who are not part of the research team. We will take many steps to prevent this from happening.

- There is a risk that other people may learn you have joined this study. However, the form you fill out and this consent form will be kept locked-up to prevent this from happening.
- There is a risk that those with access to the study data will learn who you are. To prevent this from happening we will use a special code number on all materials to protect your privacy. Results may be grouped by geographic region and/or tribe to protect your privacy.
- All researchers in this study have agreed to only study information related to this study. They can be fired or face criminal charges if they do not keep this agreement.
- Government or organizational staff at times may review studies to make sure they are being done safely and legally. If a review of this study happens, your records may be looked at. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

Will I receive any personal results from this study?

You will be provided blood pressure results obtained in clinic. After all data has been collected, you will receive additional educational material related to this study.

How will I benefit or gain from being in this research study?

You may benefit from your participation in the research by coming into the clinic for a check-up more frequently.

Who can I call if I have any questions?

If you have any questions about the study, please contact one of the researchers at (907) 729-8623 or Denise Dillard at (907) 729-8518. For questions about your rights as a study participant, contact the Alaska Area Institutional Review Board Administrator at akaalaskaarealRB@anthc.org.

This research study is:

- Looking at management of blood pressure
- Funded by the National Institutes of Health
- Completely voluntary

This research study will:

- **NOT** look at unrelated information in your medical record
- **NOT** cost you any money
- **NOT** send your name to the Washington State University
- **NOT** send personal research results to you, although you will have access to your blood pressure reading throughout the study period.

If you choose to participate, you will be asked to:

- Fill out questionnaires
- Let SCF Research see limited information from your medical record

To help locate your medical record for this study, please provide your date of birth and medical record number (if known) below.

Date of Birth: _____

Medical Record Number (Chart Number) _____

Signature below means you agree to join this study, and your questions have been answered.

[For verbal consent, read the statement and have the participant repeat the bold part below.]

I have been told about this research and all my questions have been answered. I have been offered a copy of this consent. **I agree to be in the study.**

☐ verbal consent received

Signature of Participant or Legal Representative (if in person)

Date

Signature of Research Staff

Date

Blood Pressure Monitoring Intervention for Management of High Blood Pressure among Alaska Native People

What is this research study about?

Heart disease and stroke have become leading causes of death among Alaska Native and American Indian people. High blood pressure can lead to stroke. Improving self-management of high blood pressure (hypertension) is important to reduce stroke risk, especially for Alaska Native people that have limited access to healthcare.

Please carefully read this form and ask any questions you have.

What is the goal of the research study?

The goal of this study is to improve management of high blood pressure among Alaska Native and American Indian people with high blood pressure. We plan to do this through home blood pressure monitoring and improved communication with providers and healthcare system.

Why is this research study being done here at Southcentral Foundation?

Heart disease and stroke have become leading causes of death among Alaska Native and American Indian people. The study is being done by researchers from the Southcentral Foundation Research Department and Washington State University.

Who can join the research study?

We are inviting 324 Alaska Native and American Indian people age 18 years or older that meet the following eligibility criteria to participate.

- 1) At least one visit to Southcentral Foundation or Community Health Aides last year;
- 2) At least 18 years old;

3) Diagnosis of high blood pressure and systolic blood pressure equal to or higher than 140mmHg OR systolic blood pressure 130-139mmHg plus other health conditions

OR

No diagnosis for high blood pressure but systolic blood pressure readings equal to or higher than 140mmHg OR systolic blood pressure 130-139mmHg plus other health conditions

- 4) Willingness and ability to consent;
- 5) Willingness to complete necessary data collection procedures; and
- 6) Not currently pregnant

If your blood pressure is not higher than or equal to 140mmHg or 130mmHg if there are other conditions on the first visit, you are only eligible for 1 of the 5 study visits.

Will I have to pay anything to be in this research study?

No. Participation in this study will not cost you any money.

What will I be asked to do if I join this research study?

If you decide to join this study, there will be up to 5 study visits in total. You may do these over the phone, a virtual meeting, or in person when allowed. After your first visit, you will potentially have visits at 3 months, 6 months one year later, and the final visit in-person. If you are eligible for follow up visits, you will be asked to provide contact information (name, address, phone number, email address) so that we are able to contact you.

During your visits, we will ask you to do the following things:

- Fill out a survey. It will include questions about you (e.g., age, diet, recent use of health services, tribe or Alaska Native group you belong to), and your thoughts about various ways to manage blood pressure. The questionnaire will be longer on the first and last visit.
- Allow measurement of blood pressure, height, weight, and arm.
- Take blood pressures at home at least twice daily with home blood pressure monitor.
- Share home blood pressure readings with research team and care team through the Omron Connect Wellness app and Validic or during study visits.
- Agree to receive text messages related to this study.

- Give the Southcentral Foundation and Washington State University researchers permission to have certain heart disease and blood pressure related information pulled from your medical record.

To thank you for your time and participation, you will receive a gift card at each study visit.

- \$50 gift card at the end of this 1st study visit (1.5 – 2 hours on average)

If you are eligible for the three follow-up study visits you will receive a gift card at each of these three visits.

- \$25 gift card at the end of the 2nd and 3rd study visits (30 minutes – 1 hour on average)
- \$50 gift card at the end of the final study visit. (1.5 – 2 hours on average)
- \$25 gift card at the end of the final in-person visit (20 - 30 minutes)
- At the end of the study, you will also keep the Omron home blood pressure monitor that you used in the study.

Will you be looking at my medical records?

Yes, with your permission the Southcentral Foundation Data Services Department will use your medical record number (MRN), name, date of birth, or address to access your medical record. Only information related to the purpose of this study will be collected. For example, we will look at what medicines you are taking and other health issues related to heart disease. The Data Services Department will give this information to the Southcentral Foundation and Washington State University research team. The information the researchers are given will not include your name or any other information that could identify you. You can still be in the study if you refuse to consent to the medical record review. If you would like to know all the information that we will look at, please ask the research staff member.

Can I choose not to join this research study?

Yes. You are free to join the study or not join the study. You are free to withdraw from the research project at any time. If you join the study, then decide not to give permission for the medical record review, you will not be forced to. If you choose not to join, you will not lose any benefits you are now getting at Southcentral Foundation. Your choice to join this research study will not affect whether you can join future research studies.

Are there any risks?

There is a potential risk of discomfort when the blood pressure cuff inflates and squeezes around your arm. You will be able to stop the device from inflating further if it causes discomfort.

There is a small chance that information about you could be found out by others who are not part of the Southcentral Foundation and Washington State University research team. We will take many steps to prevent this from happening.

- There is a risk that other people may learn you have joined this study. However, the form you fill out and this consent form will be kept locked-up to prevent this from happening.
- There is a risk that those with access to the study data will learn who you are. To prevent this from happening we will use a special code number on all materials to protect your privacy. Results may be grouped by geographic region and/or tribe to protect your privacy.
- All researchers in this study have agreed to only study information related to this study. They can be fired or face criminal charges if they do not keep this agreement.
- Government or organizational staff at times may review studies to make sure they are being done safely and legally. If a review of this study happens, your records may be looked at. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm

Will I receive any personal results from this study?

Yes, you will have access to your home blood pressure monitor readings throughout the study period.

How will I benefit or gain from being in this research study?

You may benefit from your participation in the research. Monitoring your blood pressure at home and improved communication with your provider may result in better management of your blood pressure.

Who can I call if I have any questions?

If you have any questions about the study, please contact one of the researchers at (907) 729-8623 or Denise Dillard at (907) 729-8518. For questions about your rights as a study participant, contact the Alaska Area Institutional Review Board at akaalaskaarealRB@anthc.org.

This research study is:

- Looking at the impact of home blood pressure monitoring and improved communication with your provider to better manage your blood pressure
- Funded by the National Institutes of Health
- Completely voluntary

This research study will:

- **NOT** look at unrelated information in your medical record
- **NOT** cost you any money
- **NOT** send your name to Washington State University
- **NOT** send personal research results to you, although you will have access to your blood pressure reading throughout the study period

If you choose to participate, you will be asked to:

- Fill out questionnaires
- Let SCF Research see limited information from your medical record
- Take blood pressure measurements at home

To help locate your medical record for this study, please provide your date of birth and medical record number (if known) below.

Date of Birth: _____

Medical Record Number (Chart Number): _____

Signature below means you agree to join this study, and your questions have been answered.

[For verbal consent, read the statement and have the participant repeat the bold part below.]

I have been told about this research and all my questions have been answered. I have been offered a copy of this consent. **I agree to be in the study.**

☐ verbal consent received

Signature of Participant or Legal Representative (if in person)

Date

Signature of Research Staff

Date